

1124/05



PTO/SB/21 (05-03)

Approved for use through 04/30/2003. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

| | | | Application Number | 10/714,591 | |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------------------------------------------------------|
| | | | Filing Date | November 14, 2003 | |
| | TRANSMITTAL | | First Named Inventor | RAMACHANDRAN, JANAI | KIRAMAN |
| | FORM | | Group Art Unit | 1616 | |
| | (to be used for all correspondence after initial | filing) | Examiner Name | Not yet assigned | |
| | Total Number of Pages in This Submission | 5 | Attomey Docket Number | GANG-006 | - |
| | * ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' | <u> </u> | RES (check all that apply) | | |
| | Fee Transmittal Form Fee Attached Amendment / Reply After Final Affidavits/declaration(s) Extension of Time Request Express Abandonment Request Supplemental Information Disclosure Statement & SB08a Form (4 pgs.) Certified Copy of Priority Documents Response to Missing Parts/ Incomplete Application Response to Missing Parts | As (fo Dri | signment Papers r an Application) awing(s) sensing-related Papers tition tition to Convert to a povisional Application wer of Attorney, Revocation ange of Correspondence dress rminal Disclaimer quest for Refund | to Group Appeal Commu of Appeals and | nication to Group rief, Reply Bricf) rmation e(s) (please |
| | under 37 CFR 1.52 or 1.53 | DE OF ARR | IOANT ATTORNEY OF | AOSHE | |
| | | | LICANT, ATTORNEY, OR | AGENI | |
| Signing ((Reg. No | Attorney/Agent CAROL L. FRANCIS, 3 BOZICEVIC, FIELD-& | | 01 | | |
| Signatur | | Juli | | | |
| Date | January 21, 2005 | | | | |

EXPRESS MAIL LABEL NO. EV 519869358 US

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Express Mail No. EV 519869358 US

| SUPPLEMENTAL | Attorney Docket | GANG-006 | |
|----------------------------------------------------------------------------|---------------------------------|---------------------------------------|--|
| INFORMATION | First Named Inventor | RAMACHANDRAN, | |
| DISCLOSURE STATEMENT | Application Number | 10/714,591 | |
| OIPE | Confirmation No. | 3234 | |
| Address to: | Filing Date | November 14, 2003 | |
| 1A11 2 4 0000 | Group Art Unit | 1616 | |
| Mail Stop Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 | Examiner Name | Not yet assigned | |
| Alexandria, VA 22313-1450 | Title: "BACTERIOP AND USES T | HAGE HAVING MODIFIED HOLIN HEREOF" | |

Sir:

This is an Information Disclosure Statement submitted for the Examiner's consideration. A Form PTO-SB/08A listing the references and copies of the cited references accompany this paper. Applicants would appreciate the Examiner's initialing and returning the form to indicate that the references have been reviewed and made of record.

This Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one of the above references constitutes prior art to the present application within the meaning of 35 U.S.C.§102.

As applicants have not yet received a first Action on the merits, no fee is believed to be required for filing this Disclosure Statement. If, however, the PTO finds that for some reason a fee is due, our Deposit Account No. 50-0815, Order No. GANG-006 may be charged thereon.

Respectfully submitted,

Registration No. 36,513

BOZICEVIC, FIELD & FRANCIS LLP

BOZICEVIC, FIELD & FRANCIS LLP

1900 University Avenue, Suite 200 East Palo Alto, California 94303

Telephone: (650) 327-3400

Facsimile: (650) 327-3231

PTO/SB/03a (08-03) Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE ersons are required to respond to a collection of information unless it contains a valid OMB control number,

Under the Paperwork JAN 2 : 2005 Complete if Known Substitute for form 1449A PEO Application Number 10/714,591 INFORMATI Filing Date November 14, 2003 First Named Inventor RAMACHANDRAN, JANAKIRAMAN Art Unit 1616 **Examiner Name** Not yet assigned (ilea ae many chaofe ae noraceary) Sheet of Attorney Docket Number GANG-006

| | | U.S. PATENT | DOCUMENTS | | |
|--------------------------|-----------------------------------------------------------|------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|--|
| Cite No. ¹ | Document Number Number-Kind Code ² (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | |
| | US- 4,957,686 | 09/18/1990 | Norris | | |
| | US- 5,688,501 | 11/18/1997 | Merril, et al. | | |
| | US- 6,121,036 | 12/19/2000 | Ghanbari, et al. | | |
| | US- 6,264,945 | 07/24/2001 | Fischetti et al. | | |
| | US2002/005802 | 05/16/2002 | Nelson et al. | | |
| | | No.1 Number-Kind Code ² (if known) US- 4,957,686 US- 5,688,501 US- 6,121,036 US- 6,264,945 | Cite No.¹ Document Number Publication Date MM-DD-YYYY US- 4,957,686 09/18/1990 US- 5,688,501 11/18/1997 US- 6,121,036 12/19/2000 US- 6,264,945 07/24/2001 | No.1 MM-DD-YYYY Applicant of Cited Document | |

| | | FOREIG | N PATENT DO | UMENTS | | |
|-----------------------|--------------|------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------------------------------------|---------------------------------------------------------------------------------|----------------|
| Examiner Initials' | Cite No.1 | Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁸ |
| | | WO 95/31562 | 11/23/1995 | Quest International B.V. | | |
| | | WO 95/27043 | 10/12/1995 | Exponential Biotherapies, Inc. | | |
| | | WO 01/82945 | 11/8/2001 | New Horizons Diagnostic Corporation | | |
| | | GB 829266 A | 03/02/1960 | | | |
| | | EP 0403292 A2 | 06/14/1990 | Microbial Development Limited | | |

| | NON PATENT LITERATURE DOCUMENTS | | | | | |
|-----------------------|---------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|--|--|--|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T² | | | |
| | | Blasi et al. "Two beginnings for a single purpose: the dual-start holins in the regulation of phage lysis" Mol Microbiol. 1996 Aug;21(4):675-82 | | | | |
| | | Blasi et al. "The C-terminal sequence of the lambda holin constitutes a cytoplasmic regulatory domain." J Bacteriol. 1999 May;181(9):2922-9 | | | | |

| Examiner | Date |
|-----------|------------|
| Signature | Considered |

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08a (08-03)

Approved for use through 07/31/2008. OMB 0651-0031

U.S. Petent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| Substitute for form 1449A/PTO | | Complete if Known | | | |
|-------------------------------|---------------------------|-------------------|------|------------------------|---------------------------|
| | | | | Application Number | 10/714,591 |
| | INFORMATION DISC | LOS | SURE | Filing Date | November 14, 2003 |
| | STATEMENT BY APP | PLIC | ANT | First Named Inventor | RAMACHANDRAN, JANAKIRAMAN |
| | | | | Art Unit | 1616 |
| | luca se manu chaate se na | 2000 | nv) | Examiner Name | Not yet assigned |
| Sheet | 2 | of | 3 | Attorney Docket Number | GANG-006 |

| | Carlton, "Phage therapy: past history and future prospects", R. M., Arch. Immunol. Ther. Exp., 47, 267(1999) |
|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | Dressman et al. "Lysis and lysis inhibition in bacteriophage T4: rV mutations reside in the holin t gene" J Bacteriol. 1999 Jul;181(14):4391-6 |
| | Grundling et al. "Holins kill without warning" Proc. Natl. Acad. Sci. USA 98:9348-52 (2001) |
| | Hori et al "Construction of self-disruptive Bacillus megaterium in response to substrate exhaustion for polyhydroxybutyrate production", Appl Microbio. Biotech 2002 59 211-216 |
| | Johnson-Boaz et al. "A dominant mutation in the bacteriophage lambda S gene causes premature lysis and an absolute defective plating phenotype", Mol Microbiol. 1994 Aug;13(3):495-504 |
| | Jain et al. "Use of lambda phage s and r gene products in an inducible lysis system for <i>vibrio</i> cholerae- and salmonella enteica serovar typhimurium-based DNA vaccine delivery systems", Infect Immun, 68, 986-89 (2000). |
| | Kutter, "Bacteriophage Therapy," at www.evergreen.edu/phage/phagetherapy/phagetherapy.html, last updated 07/14/2004 |
| | Merrill et al "Long-circulating bacteriophage as antibacterial agents", (Proc. Natl. Acad. Sci. USA 93, 3188 (1996) |
| | Miller et al. "Bacteriophage T4 genome", Microbiol Mol Biol Rev. (2003) 67(1):86-156 |
| | Martin et al. "Functional analysis of the two-gene lysis system of the Pneumococcal phage Cp-1 in homologous and heterolgous host cells" J. Bacteriol. 180:210-7 (1998) |
| | Ramanculov et al. "Functional analysis of the phage T4 holin in a lambda context," Mol. Genet. Genomics 265:345-53 (2001) |
| | Ramanculov et al. "Genetic analysis of the T4 holin: timing and toplogy" Gene 265:25-36 (2001) |
| L | |

| Examiner | Date |
|-----------|------------|
| Signature | Considered |

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08a (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

| C/fige | THE PAGE MAIN NEAGE OF ACTO | 1000, | no persons ere i | equired to respond to a collection or in | torner on on ess it contains a valid over control number. |
|-------------------------------|-----------------------------|-------------------|------------------|------------------------------------------|-----------------------------------------------------------|
| Substitute for form 1449A/PTO | | Complete if Known | | | |
| | | | | Application Number | 10/714,591 |
| 1 | INFORMATION DISC | LOS | SURE | Filing Date | November 14, 2003 |
| STATEMENT BY APPLICANT | | | | First Named Inventor | RAMACHANDRAN, JANAKIRAMAN |
| | | | | Art Unit | 1616 |
| | luca se manu chaate se na | racca | nvl | Examiner Name | Not yet assigned |
| Sheet | 3 | of | 3 | Attorney Docket Number | GANG-006 |

| | Sulakvelidze et al. "Minireview Bacteriophage Therapy", Antimicrob Agents Chemotherap, vol. 45, no. 3, pg. 649-659 (2001) | |
|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| | Sanders et al "A chloride-inducible gene expression cassette and its use in induced lysis of <i>lactococcus lactis</i> ", Appl Environ. Microbiol. 1997 63 4877-82 | |
| | Smith et al. "Purification and biochemical characterization of the lambda holin" J Bacteriol. 1998 May;180(9):2531-40 | |
| | Tan et al. "Evidence for holin function of tcdE gene in the pathogenicity of Clostridium difficile." J Med Microbiol. 2001 Jul;50(7):613-9 | |
| | Vukov et al. "Functional analysis of heterologous holin proteins in a lambdaDeltaS genetic background." FEMS Microbiol Lett. 2000 Mar 15;184(2):179-86; | |
| | Wang et al. "Holins: the protein clocks of bacteriophage infections." Annu Rev Microbiol. 2000;54:799-825 | |
| | Young, "Bacteriophage holins: deadly diversity." J Mol Microbiol Biotechnol. 2002 Jan;4(1):21-36 | |
| | | |

| | The second secon | _ |
|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|
| Examiner | Date | |
| Signature | Considered | |

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional).

Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.